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FORD, JOHN K	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/881,909	Applicant(s) Wisniewski et al.
	Examiner FORD	Art Unit 3753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 9-22-03

2a)☑ This action is FINAL. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) 1-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) 1-55 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)

16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17)☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11

18)☐ Interview Summary (PTO-413) Paper No(s). _____

19)☐ Notice of Informal Patent Application (PTO-152)

20)☐ Other:

Applicants response of September 22, 2003 (Paper No. 14) further amends claims 1 and 30. Applicants have elected Figures 1 and 2A. Applicants have elected Figures 1 and 2 and have asserted all of claims 1-55 read on the elected species in Paper No. 12 (amendment of May 12, 2003). In Paper Nos. 12 and 14, no additional illuminating disclosure of the prior art discussed in the specification other than what is discussed by Mr. Wisniewski in paragraphs 7 and 9 of the second declaration received May 12, 2003. Counsel should note that the first declaration of Mr. Wisniewski referenced in the second declaration by Mr. Wisniewski is <u>not</u> of record here and hence has not, officially been considered here. In order to expedite prosecution, however, the Examiner already has a copy of the first declaration in SN 10/057,610 and the critique of both the first and second declarations from that application are reproduced below. Evidentiary materials referred to in these critiques can be found in SN 10/057,610 or at the Integrated Biosystems website, and are not reproduced here.

Critique of the first and second declarations from SN 10/057,610>

" Applicant's first and second declarations have been received [, with the October 9, 2003 response]. In addition, applicant and counsel have stated for the record that they will not contact Genentech (Mr. Wisniewski's former employer) to obtain additional information about the prior art 1992 biopharmaceutical freezer that Mr. Wisniewski (and, apparently, Mr. Wu) developed during his employment at Genentech. In refusing the

Examiner's request to obtain the relevant dimensions of this prior art device, counsel states that it is "unnecessary and goes beyond the duty owed to the Patent Office by an inventor or their representatives." The Examiner will not make any further inquiry in light of this refusal, as apparently it would be fruitless. The tiresome inquiry has thus far yielded a few additional details from Mr. Wisniewski (e.g. the 1992 article and the 1996 Advanstar Reprint which were not originally submitted to the PTO, only the 1996 DMT article was, and the second declaration paragraph 8 admission that "I know that this distance was greater than 4 inches"), but has largely exceeded in wasted examination time what was extracted in terms of additional details about the prior art, with the exception of the 1992 article and the 1996 Advanstar equivalent.

First declaration

Paragraphs 1 – 4, no dispute.

Paragraph 5, the 1992 and its equivalent 1996 Advanstar publications were not disclosed to the PTO originally. Only a 1996 DMT article was disclosed which contains very few details of the prior art Genentech device. Only through the Examiner's inquiring was the 1992 article and its 1996 Advanstar equivalent made of record.

Paragraph 6, Mr. Wisniewski admits that he designed the internal heat transfer coil with fins for the Genentech device, the details of which he does not, now, recall. While the 1992 article does not explicitly discuss a "thermal bridge" there is nothing,

which suggests one did not form. The absence of any specific discussion is not necessarily evidence that the phenomena did not take place. It is respectfully submitted that a thermal bridge would inherently form in the 1992 Genentech device because the vessel wall during the chilling process will always be at a lower temperature that the central structure because the coldest coolant is directed to the jacket first and then the (now slightly warmed coolant) is directed to the central structure by virtue of the piping system clearly disclosed in the 1992 article.

Paragraph 7. Mr. Wisniewski's projections are no more than guesses of what the temperature distribution would be. It is respectfully submitted that these freezing phenomena are so complex that no human being including one with nearly 30 years of experience can accurately predict such results. Purporting to have such ability only diminishes ones credibility. One need not look far to see that the Examiner is correct. The Kalhori and Ramadhyani (K & R) article which involves solid phase change around a structure somewhat simpler than the 1992 Genentech device states:

"As will shortly become evident, the problem of phase change around an embedded vertical cylinder is a moving boundary problem in a complex geometry. An analysis of the problem would involve the solution of the energy equation coupled with hydrodynamic equations in the liquid phase. This is a challenging task that is amenable ***only*** to a numerical solution. Consequently, in addition to providing information of

utility in the design of thermal storage units, data from the present study could be useful in validating a numerical solution of the problem." (emphasis supplied).

Thus, researchers, other than Mr. Wisniewski, state that accurate modeling of phase change heat transfer in tanks with finned element such as shown in Figure 3 of the K & R article can only be done by computers or by direct empirical measurement.

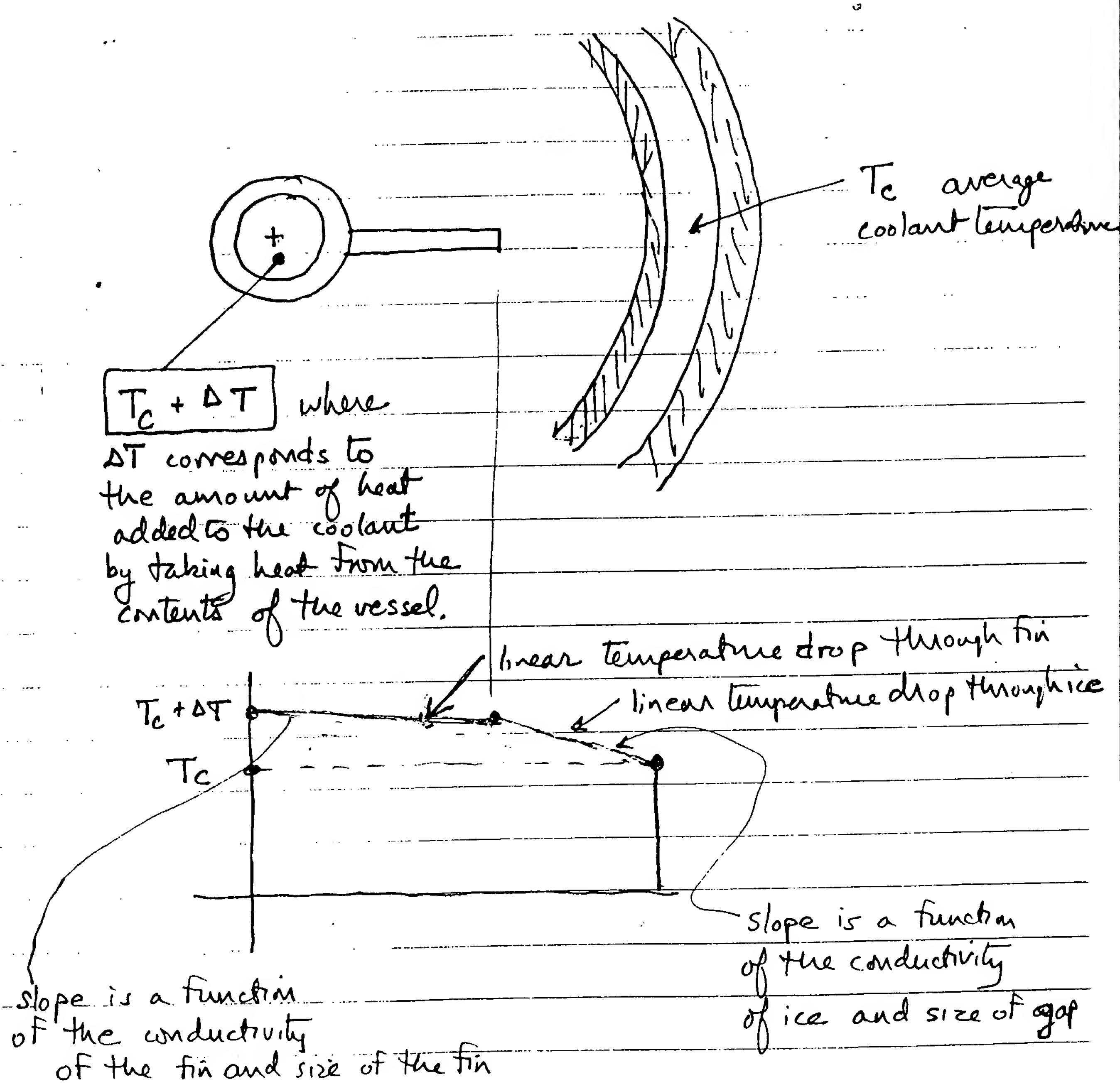
For this reason the Examiner does not find Mr. Wisniewski's thought experiments as credible evidence of what the actual temperatures are in the 1992 Genentech device. The Examiner has repeatedly asked Mr. Wisniewski to test this prior art, or a reasonable facsimile of it, using temperature transducers and Mr. Wisniewski has refused thus far.

Moreover, Exhibit B incorrectly assumes the temperature in the pipe is the same as the temperature in the jacket. This is an incorrect assumption and will necessarily lead to inaccurate conclusions. The temperature in the pipe is a complex function of the initial temperature of the coolant before it passes through the jacket, the temperature of the liquid in the container and the flow rate of the coolant among other variables. As explained above, and as shown in Figure 1 (page 134) of the 1992 article, the coolant goes from the refrigeration system to the jacket and only after exchanging heat with the contents of the vessel (and thereby acquiring some higher temperature) does it pass into the central structure where it necessarily must have a higher temperature than the

coolant in the jacket. Thus, Mr. Wisniewski's thought experiments are flawed because they are based on incorrect boundary conditions.

Paragraph 8, Exhibit C, like Exhibit B is simply a guess at what the temperature distribution actually is. As stated with respect to Exhibit B, the temperature distribution must either be measured or generated by very sophisticated computer programs, which have had their validity checked against measured data. Mr. Wisniewski has not done this. The results are not credible, for this reason.

Paragraph 9, Exhibit D is clearly erroneous, beyond the reasons stated above. Once the ice bridges the entire gap to a significant extent, the temperature distribution through a solid ice (non-moving interface) is relatively easy to predict analytically and Mr. Wisniewski's analysis can be shown to be incorrect. The correct analysis to a first approximation, which can be done by anyone of ordinary skill in the art, is given below:


T_c average coolant temperature
$\boxed{T_c + \Delta T}$ where ΔT corresponds to the amount of heat added to the coolant by taking heat from the contents of the vessel.
linear temperature drop through fin
linear temperature drop through ice
$T_c + \Delta T$
T_c
slope is a function of the conductivity of ice and size of gap
slope is a function of the conductivity of the fin and size of the fin

Paragraph 10, these allegations are not supported by valid factual materials. Mr. Wisniewski's guesswork even in declarative form is simply no substitute for real evidence. Neither he nor any other person on the planet is in a position to properly guess at the actual temperature distribution. The analysis in paragraph 10 is true no matter how large the gap is. Initially heat will be transferred from the fluid in the gap to both the fin and the wall, regardless of gap size. This process will persist longer in a large gap than a small gap but the physics of the problem is the same regardless of gap size. Applicant is free to rebut this analysis with real evidence (i.e. test results) not idle speculation.

Second Declaration

Paragraphs 1 – 4, no dispute.

Paragraph 5, Mr. Wisniewski did not disclose the 1992 article or its 1996 equivalent until the Examiner required its disclosure. Moreover Mr. Wisniewski continues to co-write articles with Mr. Wu including an article written in 2000 entitled "Scale – Down Approach to Large Volume Cryopreservation of Biopharmacenticals Using the CryoCassette and CryoWedge." Mr. Wisniewski has not contacted Mr. Wu to see what he remembers about the Genentech device inspite of repeated requests by the Examiner for additional information.

Paragraph 6, appears to refer to an office action in another application, not that mailed February 11, 2003. It is on this basis disregarded.

Paragraphs 7 and 8, for the reasons stated previously, it defies imagination that Mr. Wisniewski could remember the tip to wall distance as greater than 4 inches yet recollect nothing else about the prior art including the approximate size of the vessel (i.e. whether or not he could get his arms around it or pick it up etc.). It is also not understood why he doesn't contact Mr. Wu with whom he co-wrote an article as recently as the year 2000 to see what he remembers of the Genentech device, nor is understood why Genentech would not cooperate given that Genentech is a customer of Integrated Biosystems according to John H. Brown the president and CEO of Integrated Bio Systems. Counsel has gone on the record (Paper No. 8, page 2) stating that Genentech is a competitor of Integrated Bio system, an allegation, offered as fact, that does not appear to comport with reality. The remainder of the factual allegations in paragraph 8, which reiterate those made in the first declaration, are not credible for the reasons enumerated in the Examiner's critique of the first declaration.

Finally, as demonstrated by the article in BioPharm, Vol. 15, No. 5, May 2002, Mr. Wisniewski and his assignee have very sophisticated software and hardware at their disposal to perform the testing that the Examiner believes is required to establish the truth of the matter asserted. On page 4 of that article a CryoWedge 20 is disclosed

which appears to be used to do the sophisticated type of testing that has been studiously avoided in these applications. If Mr. Wisniewski's hand drawn sketches were accurate it is submitted that Integrated Biosystems would have no need for the Cryowedge 20 or any of the other sophisticated models and programs discussed in that article. It is also noted that Genentech is disclosed to be a customer of Integrated Biosystems not a competiter as alleged by counsel in his latest remarks (Paper No. 8, page 2, paragraph 2, line 6) calling the Genentech prior art "a competive system" Note John Brown in the Wall Street Journal interview called Genentech a customer of Integrated Biosystems. Each of these units according to Mr. Brown can cost upwards of $ 40,000 - $100,000. With those kinds of numbers and the sophisticated modeling and equipment to perform experiments that exist at Integrated Biosystems the Examiner is completely perplexed with Mr. Wisniewski's and counsel's representations that the PTO has to accept Mr. Wisniewski's hand drawn sketches based on speculative guesswork involving dubious assumptions as the best evidence applicants' possess. Clearly applicants are in a position to present much more legitimate evidence of actual temperature profiles in both their own device and in the prior art than what they have disclosed here.

Given all of the other information that has been given which is incorrect the Examiner does not see how it is possible for Mr. Wisniewski to remember that the fin tip to wall distance was greater than 4 inches yet fail to recall any other relevant dimension of the prior art (with the same degree of imprecision) including the overall size of the

tank. It does not seem plausible to the Examiner. Paragraph 8 is contradicted by the 1992 article where it is explicitly states that the fins were there to form compartments. Mr. Wisniewski's statements that they were only there to increase heat transfer contradict the 1992 article and are not credible. The conclusion, unsupported by any facts, that no thermal bridge was formed in the 1992 Genentech device is similarly not credible.

In paragraph 9, Mr. Wisniewski has simply refused to provide a sketch of the admitted prior art in the parent applications as required in Paper No. 5, page 3, lines 3 – 14. Instead USP 2,441,376 and USP 2,129,572 (references that Mr. Wisniewski was not even aware of at the time that the parent applications were written) are offered instead. Please comply with the sketch requirement. These two references do not correspond to what is disclosed to be the prior art in col. 1, line 33 – 47 of USP 6,196,296, counsel's and applicant's statements to the contrary notwithstanding. The Examiner did not ask about the prior art where the fin was attached to both walls. The Examiner asked for a specific sketch and it has not been produced.

Finally, in paragraph 10, Mr. Wisniewski simply states a conclusion without any legitimate testing to support it. Once the medium is frozen in the gap, the Genentech device will have a "thermal bridge" formed given how that term is defined in the current specification and that of the parent applications." (end of quoted section of SN 10/057,610)

In response to the second declaration by Mr.Wisniewski, it is noted that (paragraph 4) Mr. Wisniewski's prior employment at Genentech as "Principle Process Engineer" gave him unique access to the prior art machine disclosed in the 1992 article, by virtue, apparently, of his being one of its developers. It is surprising that in paragraphs 7 and 8, Mr. Wisniewski can recall so little about the machine that he apparently codeveloped. The Examiner has requested, in other related applications, Mr. Wisniewski to inquire of his former employer, Genentech, to ascertain if the dimensions of this prior art tank and its associated finned heat exchanger can be found. To the best of the Examiner's knowledge Mr. Wisniewski has not done this apparently because Genentech is a competitor of Integrated BioSystems (according to a telephone conversation the Examiner recalls with Mr. Hulton, current counsel). A search of the Internet by this Examiner does not show Genentech to be marketing (at least on the Internet) a freeze vessel resembling that disclosed in the 1992 article. The Examiner assumes that, if Genentech is using it at all, Genentech is using it internally. As referenced above Mr. Brown the CEO of Integrated Biosystems views Genentech as a customer.

In summary, beyond what is disclosed in the 1992 article, Mr. Wisniewski recalls that the "fins of the Genentech vessel were small and thin".... "and designed only to aid the freezing around the pipe loop in order to increase the relatively small surface area of the pipe (e.g. adding more cold surface area)." Mr. Wisniewski also states that "no thermal bridge" was formed in the Genentech device. Given the expansive definition of

"thermal bridge" found <u>in this specification and claims</u> the Examiner does not share in Mr. Wisniewski's conclusion that "no thermal bridge" was formed, for the reasons detailed in the rejections which follow.

Mr. Wisniewski's second declaration does not address in any way whether it would have been obvious or non-obvious to have extended the fins of the prior art to a point in close proximity to the wall or all the way to the wall and in contact there with as is currently claimed in claim 9.

Applicant has also refused to provide the Examiner with a sketch of the prior art (having both inwardly and outwardly extending fins) discussed on page 1, line 22-page 2, line 17, referencing USP 2,441,376 and USP 2129572 instead, neither of which shows the aforementioned configuration nor were they apparently known to the inventors at the time the original applications on this invention were filed.

Applicant is put on notice that, in the apparatus as claimed, patentability can not be predicted on the material intended to be processed in the container. The apparatus simply does not undergo a metamorphosis into a new apparatus simply by placing a biopharmaceutical product into it.

It is respectfully submitted that the patentability of an apparatus cannot be predicated on a new use of what is otherwise an old apparatus. This is very old case

law. See Brown v. Piper 91 U.S. 37, 23 LED. 200 (1875), and Roberts v. Ryer 91 U.S. 150, 23 LED 267 (1875). See In re Thuau 57 USPQ 324 (CCPA) 1943) for the leading new case and Ex Parte Masham 2 USPQ2d 1647 (BPAI 1987).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7-10, 12-34, 36, 37 and 39-55 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the 1992 Wisniewski and Wu article (W+W article).

As stated above, claims drawn to an apparatus, cannot predicate patentability on the material intended to be worked upon. Moreover, with regard to the recitation "thermal transfer bridge" the Examiner relies on the expansive definition given to this term in the specification on page 4, line 3 through page 5, line 16.

The Examiner does not see either in the specification or claims any limitation on the term thermal bridge that requires it to have a downward temperature gradient from the heat transfer member to the interior wall. Instead claims 1 and 30 simply state that heat must flow from the distal end to the structure to the interior wall in response to the interior wall being cooled. It is submitted that this must inherently occur in the W+W prior art. As shown in the W+W prior art cold silicon oil is first pumped to the jacket of the vessel, hence the biophamaceutical in the tank (near the walls) gets quickly cooled to the coldest temperature that the coolant oil is capable of supplying. In the process of cooling the contents of the tank the coolant oil is heated and leaves the jacket at a higher temperature than it entered the jacket. It will be at higher temperature than the bulk of the biopharmaceutical nearest the vessel wall that it just cooled. The silicon coolant oil is then (at its higher temperature) piped to the central cooling structure with its fins and will further cool the contents of the biopharmaceutical in the central portion of the tank but, by virtue of its already higher temperature, it can never cool the contents in the central portion of the tank to as low a temperature as the biopharmaceutical that was along the vessel wall. Hence, the temperature the distal edge of the fin will always be higher than at the interior side of the wall, which means that heat must be transferred from the distal edge of the fin to the interior wall of the vessel when the biopharmaceutical is frozen and cannot move, because by Fourier's Law of Heat Conduction, heat always flows from a high temperature location to a low temperature location.

Claims 1-5, 7-10, 12-34, 36-37 and 39-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of the 1992 publication by Wisniewski and Wu and the 1986 Kalhozi and Ramadhyani article entitled "Studies on heat transfer from a vertical cylinder with or without fins, embedded in a solid phase change medium" (reference 29 on page 140 of the 1992 article by Wisniewski and Wu).

The 1992 Wisniewski and Wu research paper appears to disclose every feature of the claimed invention including heat exchange member (i.e. fins) in close spaced proximity to the interior surface of the container. It lacks a "spur tube" type cooler in the center. See Figure 1 and the description thereof found on pages 134 and 136. Note page 135 should follow page 136 and was apparently printed out of order. The Examiner did not catch this error when he examined SN 08/895,782.

There is not explicit disclosure of any thermal ice bridge in the 1992 Wisniewski and Wu research paper (if that what is being claimed in the phrase "thermal transfer bridge", however see specification, page 5, lines 10-13, for apparently inconsistent definition: when the medium is being heated, after being frozen, the ice in the "gap" claimed between the tips of the fins and the wall of the container melts quickest leaving liquid in the "gap", hence it would appear that "thermal transfer bridge" is much broader term than simply an ice bridge) formed between the tips of these fins and the interior wall of the container and no explicit disclosure of how close to the container wall these heat transfer fins extend, although they must extend far enough to define

"compartments" between the fins (1992 Wisniewski and Wu research paper, page 136, first full paragraph).

The thermal bridge of ice will inherently form between the tip of the heat transfer fins and the interior of the container because they are the closest points to one another and both are actively cooled by circulating cooled silicon oil. Closely spaced cooled surfaces are known by those of skill in the refrigeration art to form ice bridges when a liquid is being frozen into a solid.

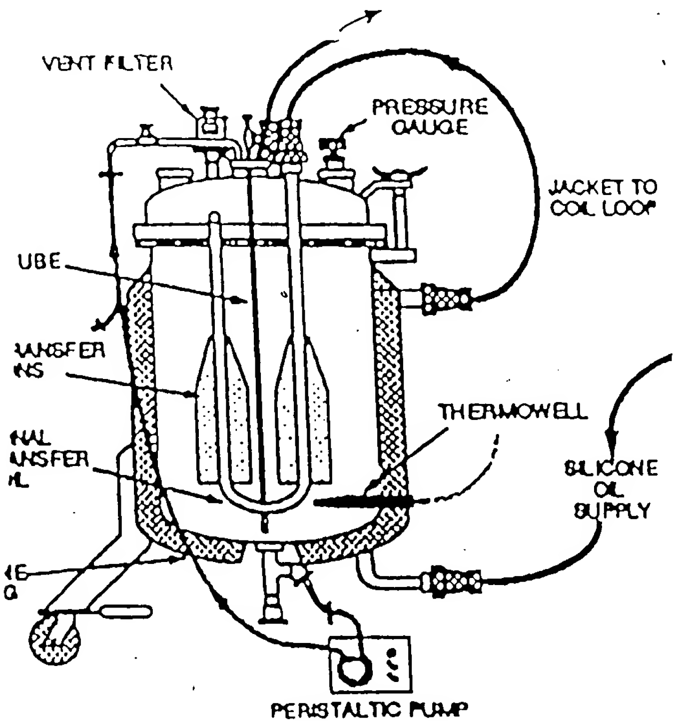
As evidence to support the Examiner's statement the closely spaced cooled surfaces will inherently form ice bridges (see MPEP 2112-2112.02, dealing with inherency, incorporated here by reference), the reader is referred to Voorhees USP 983,466 page 1, col. 2, line 97 – page 2, col. 1, line 5 (Voorhees is not relied upon explicitly here, see MPEP 2131.01, sub-section III), wherein it states:

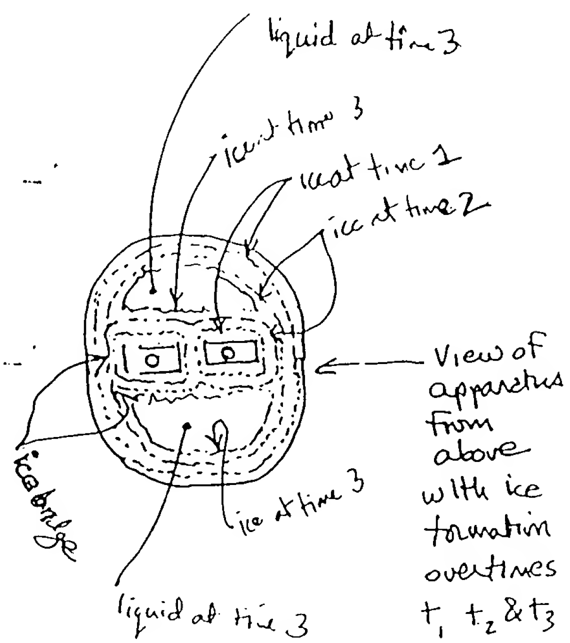
"Whether ice forms in single cakes about several freezing elements or forms in a single cake enclosing a plurality of such elements depends upon the spacing of the several freezing elements from each other. In the first instance of course, ice forms separately about each freezing element, but if these elements be **close together** the ice surrounding these element will **coalesce into a single cake;** and after this has occurred freezing will go on from the surface of the combination cake so formed" (Emphasis supplied).

Furthermore, Voorhees, page 2, col. 1, lines 14-21 states: "I have shown a number of other elements so spaced relatively as to from a single cake 15 of length comparable to cakes formed in plate processes. Of course if the **freez-ing were continued indefinitely the cakes 12,13, 14 and 15 would eventually coalesce and freeze to the sides of the tank..."**

It is evident that ice will build upon the heat exchanger and walls of the vessel shown in Figure 1 of 1992 Wisniewski and Wu research paper, during the freezing phase, until they bridge as shown in the diagrams below, a fact that can be established by basic scientific principles. Burroughs et al. USP 3,318,105 illustrates the phenomena. As is clearly seen in Figs. 1A-1C ice builds up evenly cooled surfaces and even as the top surface freezes the ice coating on the submerged surfaces continues to build up more or less evenly. The same type of analysis is disclosed by Finnegan USP 2,129,572, illustrating that the time required to freeze a substance varies "approximately as the square of the thickness of such substance" with slower freezing generally leading to undesirable concentration effects (what applicants and the 1992 Wisniewski and Wu research paper refer to as "cryoconcentration"). Finnegan, like the 1992 Wisniewski and Wu research paper, discloses the use of heat exchange fins (projecting inwardly from the exterior wall of the container in the case of Finnegan) to form compartments within the tank to speed the freezing process. Finnegan illustrates using a series of dotted lines how the freezing process progresses over time in various geometries of

heat exchange fins. Applying this same science (illustrated by Burroughs and Finnegan) to the system disclosed by 1992 Wisniewski and Wu research paper yield the results illustrated on the next page for the system disclosed by the 1992 Wisniewski and Wu research paper in Figure 1.





Even if the 1992 Wisniewski and Wu research paper is deemed not to disclose heat exchanger fins “in close spaced proximity” to the container wall, to have extended fins in Figure 1 of the 1992 Wisniewski and Wu publication to a point “in close spaced proximity” to the interior surface to the container in order to advantageously increase the rate of heat transfer and “divide the tank volume into compartments to

decrease the freezing the thawing time and to reduce cryoconcentration effects" (1992 publication, page 136, col. 1, first full paragraph) would have been obvious to one of ordinary skill in the art.

The examiner submits that the fins shown in Figure 1 of the 1992 Wisniewski and Wu publication are already in spaced proximity to the interior wall of the container such that substantially discrete compartments are formed (see page 136, col. 1, first full paragraph) an effect that would be enhanced if the fins were further extended to a point closer to the interior wall of the container.

Moreover, larger fins would increase the amount of surface area for heat transfer, giving an added advantage. On page 136 of the 1992 Wisniewski and Wu publication it states that the "fin's length, thickness and shape were designed to maintain **efficient heat transfer** during freezing and thawing." (Emphasis supplied). It is not open to any serious debate that larger, thicker, fins that extend to points closer to the interior wall of the container are more efficient heat transfer vehicles than smaller, thinner fins that do not extend to points closer to the interior wall of the container.

The 1992 Wisniewski and Wu publication states on page 136: "The heat transfer fins were configured to **divide the tank into compartments** to decrease the freezing and thawing time and to reduce cryoconcentration effects. **Compartmentation** of the tank is especially effective for maintaining liquid in a static state to minimize

cryoconcentration." (Emphasis supplied). The fins are designed to maintain "efficient heat transfer during freezing and thawing" (page 134, col. 2, 1992 Wisniewski and Wu publication). Figure 1 (page 134) of the 1992 Wisniewski and Wu publication clearly shows heat transfer fins extending outwardly for the internal heat transfer coil towards the interior wall of the container. Extending the fins further outwardly to aid in the formation of compartments to minimize cryoconcentration would have been another motivation to one of ordinary skill in the art to make the same modification.

The 1986 Kalhori and Ramadhyani article entitled "Studies on heat transfer from a vertical cylinder, with or without fins, embedded in solid phase change medium" (reference 29, on page 140 of the 1992 article by Wisniewski and Wu), like applicant have disclosed in Figures 1 & 2 of their drawings, shows in Figure 3 a "spur-tube" type heat exchanger with six heat transfer fins welded to it in a manner almost identical to what applicants show in Figures 1 and 2 of the current application. The finned heat exchanger as shown is immersed in a container of paraffin and the melting and freezing processes were studied in great detail with a material, paraffin, of known characteristics. See the abstract of this article on the first page. Again, fins that span nearly the entire interior of the container were found to be especially effective, with a host of definitive technical data presented (that is unnecessary to discuss here) showing the virtues of these large fins in improving heat exchange. See last sentence of article – "In view of the **superior heat transfer characteristics, the finned cylinder** is a much better choice of the design of a practical thermal storage unit." (Emphasis supplied).

In view of each of the above teachings, it would have been obvious to one of ordinary skill in the art to have extended the fins of the prior art disclosed in the 1992 article by Wisniewski and Wu to substantially the inner periphery of the container, leaving a small gap to permit the heat exchanger to be removed for cleaning (as is disclosed to be necessary in the 1992 article by Wisniewski and Wu page 136). Extending the fins to substantially the inner periphery of the container would:

a. Improve heat transfer by increasing heat transfer surface area and
b. Improve "compartmentation" by forming ice bridges.

In addition, to have replaced the centrally mounted heat exchanger and fins of the 1992 article by Wisniewski and Wu disclosed in Figure 1 with the heat exchanger and fins shown by Kalhori and Ramandhyani in Figure 3 to improve heat transfer and to facilitate ease of construction as well as to facilitate easy removal form the frozen mass would have been obvious to one of ordinary skill in the art.

Claims 1-5, 7-10, 12-34, 36-37 and 39-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over the 1992 publication by Wisniewski and Wu and/or 1986 Kalahari and Ramadhyani article as applied to claims 1-5, 7-10, 12-34, 36-37 and 39-56 above, and further in view of: Euwema (USP 3,550,393), Cothern et al (USPN

5,535,598), West (USPN 2,114,642), Morrison (USPN 1,874,578) and Nakao (JP 57-58087).

Euwema discloses ice bridges forming at the ends of vanes 36 and 38 when wall 10 is cooled by a refrigerant. See column 3, lines 4-19. The ice is shown at 18 (Figure 1) and rapidly bridges the gap between the tips of vanes 36 and 38 and the cooled surfaces 10 of the refrigeration device (Figure 2) in much the same manner that applicants disclose in their specification with regard to ice forming in the gap between the tips of their fins 8 and the inner wall of their container. Euwema's ice divides the regions on either side of vanes 36 and 38 into separate compartments to facilitate improved heat exchange with the liquid in those compartments. In other words, the ice bridges in Euwema prevent the fluids in the compartments on either side of vanes 36 and 38 from intermixing in much the same manner that the 1992 publication by Wisniewski and Wu, page 136, first full paragraph – "The heat transfer fins were configured to divide the tank volume into compartments to decrease the freezing and thawing time and to reduce cryoconcentration effects").

Likewise, Cothern et al teaches (Figures 1–3) a jacketed tank (Figure 2) similar to applicants and a <u>fin-like heat exchanger formed with plates</u> that divide the interior of the tank into a number of compartments by spanning nearly the entire tank to areas very close (close spaced gaps) to the sidewalls of the tank (in much the same manner applicants disclose, albeit in a square as opposed to a round tank). These large heat

exchanger plates provide great surface area for improved freezing as discussed by Cothern in column 7, lines 46-52. In Cothern, having these closely spaced gaps between the distal ends of the immersed heat exchanger and the walls of the jacketed tank permits the heat exchanger to be withdrawn easily for cleaning and reduces the need for tight manufacturing tolerances in the immersed heat exchanger fit tightly into the tank and form fully non-communicating compartments, ample reason to use similar construction of a gap in the W+W prior art.

West in Figures 5 and 6 illustrates a fast freezing system which freezes the substance so fast that there are no cryoconcentration effects. See page 2, lines 60-66 and lines 70-72. The periphery of the heat exchanger structure 15 is clearly spaced from the container 8. In Figure 6 the freezing is applied to both the inside and outside of the container to further reduce cryoconcentration effects. See page 2, the last three paragraphs of the specification.

Morrison also teaches that fins 7 spanning nearly the entire interior of a container (which container is believed to be shown in phantom lines in Figure 1) "insure maximum heating or cooling surface, so that operation of the device may be carried out with facility" (Morrison, column 1, lines 8-13).

Finally, Nakao teaches metallic fins 5 spanning nearly the entire interior of a container having a phase-change material therein. A relatively small gap exists between

the end of these fins and the wall of the container. These fins greatly aid in the transfer of heat introduced at, and removed from, the periphery of the container.

In view of each of the above teachings, it would have been obvious to one of ordinary skill in the art to have extended the fins of the prior art disclosed in the 1992 article by Wisniewski and Wu to substantially the inner periphery of the container, leaving a small gap to permit the heat exchanger to be removed for cleaning (as is disclosed to be necessary in the 1992 article by Wisniewski and Wu, page 136).

Extending the fins to substantially inner periphery of the container would:

a. Improve heat transfer by increasing heat transfer surface area as taught by any one of Cothern, West, Morrison and Nakao

b. Improve "compartmentation" by forming ice bridges as explicitly taught by Euwema and

c. Eliminate cryoconcentration effects as taught by West.

In addition, to have replaced the centrally mounted heat exchanger and fins of the 1992 article by Wisniewski and Wu disclosed in Figure 1 with the heat exchanger and fins shown by Kalhori and Ramadhyani in Figure 3 to improve heat transfer and to facilitate ease of construction as well as to facilitate easy removal form the frozen mass would have been obvious to one of ordinary skill in the art.

Cothern in column 7, line 54 – column 8, line 8 teaches various controls for controlling both rate and cooling direction in a freeze container by varying refrigerant flow in the various portion of the device. To the extent that they system disclosed by applications can accomplish the functions set forth in the claims it would have been obvious to have configured the 1992 Wisniewski and Wu prior art with suitable controls to achieve the same end (those controls being broadly taught by Cothern). Since applicants' own specification is virtually devoid of how these functions are accomplished it must be surmised that obtaining these results must be within the skill of those skilled in the refrigeration art.

Claims 1-5, 7-10, 12-34, 36-37 and 39-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of the prior as applied to claims 1-5, 7-10, 12-34, 36-37 and 39-56 above, and further in view of the conceded prior art discussed on pages 1, line 22 – page 2, line 17 of the specification.

For the sake of completeness, even though the Examiner is unsure of the precise nature of applicant's admitted prior art, it appears that placing a heat exchanger structure with fins on it into a conditioned container is known however in this prior art the fins are attached to both the wall of the container and the heat exchange structure making routine removal of the finned heat exchange structure impossible. Such a deficiency however does not seem to be precluded by most of the claims and even as

to those which do claim non-attachment of the heat exchange structure to the tank wall, such a fairly taught by the 1992 Wisniewski and Wu article.

Claim 11 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of the prior art as applied to claim 1 and 30 above, and further in view of Brown or Gross.

Brown (Fig 2) and Gross (Fig 24) each teach means forming spiral paths on the outside of a tank. To have configured the 1992 Wisniewski and Wu prior art with a spiral path on the outside of the tank would have been obvious to improve heat exchange.

Claims 6 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of the prior art as applied to claims 1 or 30 above, and further in view of Nagashio or Koerber.

Nagashio and Koerber disclose removable liners for large tanks particularly for cleaning and leakage prevention. To have used such liners in the tanks disclosed in the prior art advantageously permit fast cleaning and low leakage would have been obvious.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to John Ford at telephone number 703-308-2636.

John K. Ford
Primary Examiner